

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

TAKEDA PHARMACEUTICAL CO.,
LTD., et al.,

Plaintiffs,

v.

SANDOZ, INC.,

Defendant.

Case No. 12-00446 JCS

CLAIM CONSTRUCTION ORDER

I. INTRODUCTION

Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals U.S.A., Inc. (formerly known as Takeda Pharmaceuticals North America, Inc.), Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (hereinafter, referred to collectively as “Takeda”) initiated this patent infringement action under 35 U.S.C. § 271(e)(2), a provision of the Hatch-Waxman Act, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, in response to Abbreviated New Drug Applications (“ANDA”) No. 203-504, submitted to the U.S. Food and Drug Administration (“FDA”) by Sandoz, Inc. (“Sandoz”). In its ANDA, Sandoz seeks FDA approval to manufacture and sell a generic version of Takeda’s drug DEXILANT (dexlansoprazole), a prescription drug used to treat acid reflux disease.

Takeda owns several patents related to dexlansoprazole that it asserts are infringed by Sandoz’s ANDA product, including U.S. Patent No. 7,790,755 (“the ’755 Patent”). In this Order, the Court construes the claim term “said polymeric substance” in claim 1 of the ‘755 Patent. Pursuant to the parties’ stipulation, the hearing set for May 9, 2013 at 1:30 p.m. was vacated.

II. BACKGROUND

The ’755 Patent relates to controlled-release compositions for imidazoles, a class of

compounds of which dextansoprazole is a member. The asserted claims of the '755 Patent are specifically directed at a capsule that uses a dual-delayed release mechanism with two different types of "tablets, granules, or fine granules" (hereinafter referred to as "granules"), each with a different type of enteric coating. Claim 1 describes the compositions and enteric coatings as follows:

A capsule comprising:

composition (i) comprising a tablet, granule or fine granule in which a release of an active ingredient is controlled; said tablet, granule or fine granule comprising a core particle containing an imidazole compound [having a chemical formula specified in the claim] and

a pH-dependently soluble release-controlled coating-layer which comprises **one kind of polymeric substance or a mixture of two or more kinds of polymeric substances having different release properties** selected from the group consisting of hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, carboxymethylethyl cellulose, methyl methacrylatemethacrylic acid copolymer, methacrylic acid-ethyl acrylate copolymer, methacrylic acid-methyl acrylate-methyl methacrylate copolymer, hydroxypropyl cellulose acetate succinate, polyvinyl acetate phthalate and shellac; **said polymeric substance** is soluble in the pH range of 6.0 to 7.5, and

composition (ii) comprising a tablet, granule or fine granule comprising a core particle containing the active ingredient and enteric coat such that the active ingredient is released in the pH range of no less than 5.0 to no more than 6.0.

'755 Patent, claim 1 (emphasis added). The Court refers to composition (i) as the "high-pH granule" and composition (ii) as the "low-pH granule" based on the pH ranges specified in the claim for the two compositions.

The parties dispute the meaning of the claim term "said polymeric substance" (in bold). In its opening brief, Takeda contends it refers to the phrase that precedes it in claim 1 (also in bold) and thus means "said polymeric substance or mixture of two or more kinds of polymeric substances." Takeda's Opening Claim Construction Brief ("Takeda Opening Brief") at 11-12 (citing *Baldwin Graphic Systems, Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1340 (Fed. Cir. 2008)). According to Takeda, *Baldwin* stands for the proposition that where a claim term using "said" refers back to an antecedent phrase that "carries no definitive numerosity," the claim term also is not limited as to numerosity. *Id.* Here, Takeda asserts, the case is even stronger than *Baldwin* for

finding that “said polymeric substance” may encompass either a single polymeric substance or a mixture of two polymeric substances because the antecedent phrase makes this clear rather than simply leaving the numerosity undefined. *Id.* at 13.

Takeda also cites the following passage in the specification that it contends supports its position that “said polymeric substance” can be a single substance or a combination of the two:

As a coating material for controlling pH-dependently the release of medical active ingredient, polymers such as hydroxypropyl methylcellulose phthalate (HP-55, HP-50 manufactured by Shin-Etsu Chemical Co., Ltd.), cellulose acetate phthalate, carboxymethyl ethylcellulose (CMEC manufactured by Freund Industrial Co., Ltd.), methyl methacrylate-methacrylic acid copolymer (Eudragit L100 (methacrylic acid copolymer L) or Eudragit S100 (methacrylic acid copolymer S); manufactured by Rohm Co.), methacrylic acid-ethyl acrylate copolymer (Eudragit L100-55 (dried methacrylic acid copolymer LD) or Eudragit L30D-55 (methacrylic acid copolymer LD); manufactured by Rohm Co.), methacrylic acid-methyl acrylate-methyl methacrylate copolymer (Eudragit FS30D manufactured by Rohm Co.), hydroxypropyl cellulose acetate succinate (HPMCAS manufactured by Shin-Etsu Chemical Co., Ltd.), polyvinyl acetate phthalate and shellac are used. . . . **The polymer as the above-mentioned coating material may be used alone or at least 2 or more kinds of the polymers may be used to coat in combination,** or at least 2 or more kinds of the polymers may be coated sequentially to prepare multi-layers.

Takeda Opening Brief at 13 (quoting ‘755 Patent, col. 9, ll. 42-65) (emphasis in Takeda Opening Brief). Takeda argues that the word “polymer” in this passage is used in the same way as the term “polymeric substance” in claim 1 and shows that the inventors used that word to refer to a single substance or a mixture of two substances. *Id.* at 13.

In its responsive brief, Sandoz argues that the claim term is insolubly ambiguous because a person skilled in the art would not know if it refers only to “one kind of polymeric substance” or also to the “mixture of two or more kinds of polymeric substances.” Defendant Sandoz, Inc.’s Responding Claim Construction Brief (“Sandoz Responsive Brief”) at 4. Thus, according to Sandoz, to the extent claim 1 identifies a pH range at which “said polymeric substance” is soluble (that is, between pH 6.0 and 7.5), a person skilled in the art would not know if the claim requires that: 1) one kind of polymeric substance be soluble in this range; 2) the *mixture* of two or more polymeric substances having different release properties be soluble in this range; 3) *each* of the constituent polymers in the mixture of polymers be soluble in this range; or 4) *any* of the

1 constituent polymers in the mixture of two or more polymers be soluble in this range. *Id.* at 4-5.
 2 According to Sandoz, “neither the patent itself nor the prosecution history provides answers to
 3 these questions.” *Id.* at 5. Nor is it clear what “different release properties” of the constituent
 4 polymers are covered by the claim when a mixture of substances is used, Sandoz asserts. *Id.*
 5 Sandoz also challenges Takeda’s assertion that it is clear that “said polymeric substances” refers to
 6 both a single polymer and a mixture of polymers, arguing that it is unclear whether “said
 7 polymeric substances” refers to “one kind of a polymeric substance” or to both a single polymeric
 8 substance and a mixture of polymeric substances. *Id.*

9 Sandoz also argues that *Baldwin* is not on point because in that case the antecedent phrase
 10 referred to “a pre-soaked fabric roll” and the disputed claim term was “said fabric roll.” *Id.* at 5-6
 11 (citing 512 F.3d at 1342-1343). Thus, that case addressed the question of whether the indefinite
 12 article “a” in the antecedent phrase meant that the term “said fabric roll” should be construed as
 13 being limited to the singular form. *Id.* at 6. Sandoz points out that here, there is no indefinite
 14 article at issue. *Id.* Instead, the claim language indicates that “said polymeric substance” could be
 15 either one polymer or a mixture of two polymers. Therefore *Baldwin* is not relevant, Sandoz
 16 contends. *Id.* at 6.

17 Sandoz asserts that when the patentee wanted to cover mixtures, it knew how to do so.
 18 Sandoz cites as an example the phrase “one kind of polymeric substance or a mixture of two or
 19 more kinds of polymeric substances” in claim 1. *Id.* Sandoz argues that had the patentees wanted
 20 to cover both a single polymeric substance and a mixture, they could have claimed “said
 21 polymeric substance *or a mixture of two or more kinds of polymeric substances* is soluble in the
 22 pH range of 6.0 to 7.5.” *Id.* at 6 (emphasis in brief).

23 Sandoz asks the Court to find the term “said polymeric substance” insolubly ambiguous or,
 24 in the alternative, to defer ruling on the issue until summary judgment in light of the “highly
 25 factual nature of this inquiry.” *Id.*

26 In its Reply brief, Takeda argues that Sandoz has offered no evidence, including expert
 27 evidence, that a person of ordinary skill in the art would not understand the meaning of the
 28 disputed claim term. Takeda’s Reply Brief on Claim Construction (“Takeda Reply Brief”) at 1-2.

1 Takeda asserts the lawyer’s argument offered by Sandoz fails to meet the heavy burden necessary
 2 to prove indefiniteness by clear and convincing evidence. *Id.* at 2. Takeda rejects Sandoz’s
 3 assertion that the claim language is unclear and reiterates its argument that “the term ‘said’ is an
 4 anaphoric phrase that merely refers back to the initial antecedent phrase” and under *Baldwin*, the
 5 scope of the anaphoric phrase is the same as that of the antecedent phrase. *Id.* Takeda again
 6 points to col. 9, lines 42-65 of the specification in support of its position. Takeda also cites the
 7 following definition of “pH-dependently” in the specification:

8 the coating material is dissolved/eluted under the circumstances of
 9 more than a certain pH value to release an active ingredient. . . .
 10 [T]he **coating material** of the present invention is preferably a
 11 **substance** which is dissolved at a higher pH (preferably a pH of 6.0
 or above and 7.5 or below, and more preferably a pH of 6.5 or above
 and below 7.2) and controls more favorably the release of drug in
 the stomach.

12 Takeda Reply Brief at 4 (quoting ‘755 Patent, col. 9, ll. 32-41) (emphasis in brief). According to
 13 Takeda, this passage makes clear that the pH-dependent release of the active ingredient is
 14 controlled by the “coating material,” “regardless of whether it is made up of a single polymer or a
 15 combination of two or more polymers.” *Id.* Takeda argues further that this interpretation is
 16 consistent with claim 7 of the ‘755 Patent, which “further specifies that the coating ‘*layer*’ of the
 17 high-pH granule is ‘soluble in the pH range of no less than 6.5 to no more than 7.0. . . . instead of
 18 stating as in claim 1 that the *polymeric substance* in the coating layer is soluble in the claimed pH
 19 range.” *Id.* at 4 (emphasis in brief).

20 Takeda also argues that the defendants in Case Nos. C-11-0840, C-11-1609 and C-11-1610
 21 (hereinafter, “the Related Cases”) understood that the “claimed pH range for the high-pH granule
 22 applies to any and all polymers in the coating layer,” citing as an example an argument made by
 23 TWi during claim construction that claim 1 of the ‘755 Patent “contemplated a ‘determin[ation]
 24 whether the **polymer or mixture of polymers** listed in the claim 1 Markush group **are soluble** at
 25 a specified pH.”” *Id.* (quoting Claim Construction Order in Case No. 11-00840, Docket No. 106
 26 (emphasis in Takeda Reply Brief)). Takeda notes that Sandoz seems to share this understanding,
 27 pointing to a statement in Sandoz’s brief that the claimed pH range applies to the “solubility of the
 28 **coating layer**,” which the patentee “defined[] as comprising ‘one kind of polymeric substance or a

1 mixture of two or more kinds of polymeric substances.” *Id.* (citing Sandoz Responsive Brief at
2 6).

3 Takeda also rejects Sandoz’s contention that it is unclear what “different release
4 properties” are referred to in claim 1. *Id.* at 4-5. According to Takeda, it would be clear that this
5 phrase refers to the different target pH levels that the polymers listed in claim 1 may exhibit. *Id.*
6 In support of this contention, Takeda cites col. 10, ll. 2-7 of the ‘755 Patent (“[f]urther, more
7 desirably, a polymer soluble at a pH of 6.0 or above and a polymer soluble at a pH of 7.0 or above
8 are used in combination . . .”) and claim 8 (further specifying a “pH-dependently soluble release-
9 controlled coating-layer contains a mixture of two or more kinds of methyl methacrylate-
10 methacrylic acid copolymers having **different release properties**). *Id.*

11 Takeda argues that the claim term “said polymeric substance” has a reasonably
12 ascertainable meaning in the context of the claim language and the patent as a whole and therefore
13 is not indefinite. *Id.* at 5 (citing *Energizer Holdings, Inc. v. Int’l Trade Comm’n*, 435 F.3d 1366,
14 1370 (Fed. Cir. 2006)). Takeda also asserts that this issue should not be deferred to summary
15 judgment in light of Sandoz’s failure to present any evidence that the claim term “said polymeric
16 substance” is indefinite. *Id.*

17 **III. LEGAL STANDARD**

18 **A. CLAIM CONSTRUCTION STANDARDS**

19 “It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to
20 which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312
21 (Fed. Cir. 2005) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d
22 1111, 1115 (Fed. Cir. 2004)). Generally, claim terms are given the ordinary and customary
23 meaning that would be ascribed to them by a person of ordinary skill in the field of the invention.
24 *Id.* at 1312- 1313; see also *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir.
25 2001)(“[U]nless compelled to do otherwise, a court will give a claim term the full range of its
26 ordinary meaning as understood by an artisan of ordinary skill”).

27 The most “significant source of the legally operative meaning of disputed claim language”
28 is the intrinsic evidence of record, that is, the claims, the specification and the prosecution history.

1 *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). This is because “the
2 person of ordinary skill in the art is deemed to read the claim term not only in the context of the
3 particular claim in which the disputed term appears, but in the context of the entire patent,
4 including the specification.” *Phillips*, 415 F.3d at 1313. In some cases, the specification may
5 reveal a “special definition” given by the inventor that differs from the meaning the term might
6 otherwise possess. *Id.* at 1316. In such instances, “the inventor’s lexicography governs.” *Id.*
7 Similarly, a specification may reveal “an intentional disclaimer, or disavowal, of claim scope by
8 the inventor.” *Id.*

9 A person of ordinary skill in the art also looks to the prosecution history of a patent to
10 understand how the patent applicant and the Patent Office understood the claim terms. *Id.* at 1313,
11 1317. Arguments and amendments made during patent prosecution limit the interpretation of
12 claim terms to exclude interpretations that were disclaimed to obtain allowance of a claim.
13 *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995).

14 While claims are to be construed in light of the specification, courts must be careful not to
15 read limitations from the specification into the claim. *Phillips*, 415 F.3d at 1323. Thus, for
16 example, if a patent specification describes only a single embodiment of a claimed invention, that
17 does not mean the claims of the patent necessarily must be construed as limited to that
18 embodiment. *Id.* Rather, it is understood that the purpose of the specification “is to teach and
19 enable those of skill in the art to make and use the invention” and that sometimes, the best way to
20 do that is to provide an example. *Id.*

21 Courts may also use extrinsic evidence in construing claim terms if it is necessary, so long
22 as such evidence is not used to “vary or contradict the terms of the claims.” *Markman v Westview*
23 *Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995). As the court explained in *Markman*,
24 “[extrinsic] evidence may be helpful to explain scientific principles, the meaning of technical
25 terms, and terms of art that appear in the patent and prosecution history.” 52 F.3d at 980. The
26 Federal Circuit has warned, however, that such evidence is generally “less reliable than the patent
27 and its prosecution history in determining how to read claim terms.” *Phillips*, 415 F.3d at 1318.
28 Thus, courts are free to consult dictionaries and technical treatises so long as they are careful not

to elevate them “to such prominence . . . that it focuses the inquiry on the abstract meaning of the words rather than on the meaning of claim terms within the context of the patent.” *Id.* at 1321-22.

B. INDEFINITENESS STANDARDS

The requirement that claims be sufficiently “definite” is set forth in 35 U.S.C. § 112, ¶ 2, which provides that, “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” “The definiteness inquiry focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification.” *Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001). In order to “accord respect to the statutory presumption of patent validity,” a claim should be found indefinite “only if reasonable efforts at claim construction prove futile.” *Exxon Research and Engineering Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). A claim is not indefinite simply because its meaning is not ascertainable from the face of the claims. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1311, 1342 (Fed. Cir. 2003). Nor is a claim indefinite simply because it covers “some embodiments that may be inoperable.” *Exxon Research and Engineering Co.*, 265 F.3d at 1382. A claim is indefinite, however, if it is “insolubly ambiguous, and no narrowing construction can properly be adopted.” *Amgen*, 314 F.3d at 1342 (citations omitted). To establish that a claim is indefinite an alleged infringer must “demonstrate by clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art.” *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010).

IV. ANALYSIS

Sandoz’s indefiniteness argument is premised on the bare assertion that a person skilled in the art would not be able to determine whether “said polymeric substance” refers to “one kind of polymeric substance or a mixture of two or more kinds of polymeric substances having different release properties.” Sandoz does not point to any expert testimony to support its claim; nor does it address the passages in the specification cited by Takeda -- along with the claim language itself --

1 which support a contrary conclusion.

2 First, the Court looks to the claim language, which recites: a “pH dependently soluble
3 release-controlled coating layer which comprises one kind of polymeric substance or a mixture of
4 two or more kinds of polymeric substances having different release properties” and later states that
5 “said polymeric substance is soluble in the pH range of 6.0 to 7.5.” While perhaps inartfully
6 drafted, these phrases in claim 1 support the conclusion that “said polymeric substance” refers
7 back to the “coating layer” comprised of either one polymeric substance or a mixture of two or
8 more polymeric substances. This reading is consistent with the *Baldwin* decision. *See* 512 F.3d
9 1338 (Fed. Cir. 2008). Although Sandoz is correct that the holding in that case turned on the use
10 of the indefinite article “a” -- in contrast to the claim language at issue here -- the Court agrees
11 with Takeda that *Baldwin* also stands for a broader proposition, namely, that where a claim term
12 uses “said” to refers back to an earlier phrase in the claim, the scope of the term will be the same
13 as the scope of the earlier language. *See* 512 F.3d at 1342-1343. In this case, the claim term thus
14 encompasses both a single polymeric substance and a mixture of two or more kinds of polymeric
15 substances having different release properties.

16 The ‘755 specification also supports this conclusion. At column 9, ll. 42-63, the patentee
17 made clear that the polymers served as coating material and that the “polymer as the above-
18 mentioned coating material may be used alone or at least 2 or more kinds of the polymers may be
19 used to coat in combination.” Similarly, in column 9 at ll. 32-41, the patentee stated that “the
20 coating material of the present invention is preferably a substance which is dissolved at a higher
21 pH (preferably a pH of 6.0 or above and 7.5 or below . . .).” These passages indicate that the
22 substance recited in claim 1 as “said polymeric substance” and which is soluble in the pH range of
23 6.0 to 7.5 may consist of a single polymer or a mixture of polymers. The Court also agrees with
24 Takeda that the phrase “having different release properties,” when read in light of the
25 specification, refers to the pH levels at which the polymers dissolve. *See, e.g.,* ‘755 Patent, col.
26 10, ll. 2-7.

27 Finally, the Court notes that Sandoz has not offered any extrinsic evidence that suggests
28 that the claim term is indefinite. Given that the Court finds the meaning of the claim to be clear in

light of the intrinsic evidence and Sandoz has not pointed to any evidence (intrinsic or extrinsic) that demonstrates the existence of a fact question on this issue, the Court declines Sandoz's invitation to defer ruling on its indefiniteness challenge until summary judgment.

V. CONCLUSION

For the reasons stated above, the Court finds that the claim term "said polymeric substance" is not indefinite and construes that term as "said polymeric substance or mixture of two or more kinds of polymeric substances."

IT IS SO ORDERED.

Dated: May 16, 2013


JOSEPH C. SPERO
United States Magistrate Judge

United States District Court
Northern District of California